

CLAIMS

1. An assay device comprising liquid transport means adapted to take up a liquid sample and conduct the liquid to an analyte detection region operable to provide a test signal indicative of the presence and/or amount of an analyte in the liquid sample; characterised in that the assay device further comprises a sample presence signal generation means.
2. The assay device of claim 1 characterised in that the sample presence signal generation means generates a sample presence signal in the analyte detection region.
3. The assay device of claim 1 or claim 2 wherein the sample presence signal generation means generates a sample presence signal which interacts with the test signal in the presence of analyte to form an interactive symbol representative of a positive result.
4. The assay device of any one of claims 1, 2, or 3 wherein the sample presence signal is not generated by means of an immunoreaction.
5. The assay device of any one preceding claim wherein the sample presence signal is in the form of a line oriented substantially parallel with the direction of flow of the liquid sample.
6. The assay device of claim 5 wherein the test signal is a line oriented substantially perpendicular to the sample presence line such that the test signal intersects the sample presence signal.
7. The assay device of claim 5 or claim 6 wherein the test signal is in the form of a clear, unambiguous line without fadeout.

8. The assay device of any one preceding claim having a casing, the casing having a window therein through which the test signal and sample presence signal are viewable when formed.
9. The assay device of any one preceding claim further comprising a control signal generation means downstream of the analyte detection region adapted to generate a control signal indicative that one or more reagents present in the assay device are functioning.
10. The assay device of any one preceding claim having a surface visible to the user, wherein the sample presence signal generation means comprises a coloured portion which is not on the surface visible to the user and which is overlaid by a material which, when dry, is substantially opaque and which initially obscures at least a part of the coloured portion but which, when wet, becomes sufficiently translucent or transparent to allow at least the initially obscured part of the coloured portion to become visible to the user.
11. The assay device of claim 10 wherein the coloured portion is a surface of a protruberance from a casing provided around the liquid transport means.
12. The assay device of claim 10 or claim 11 wherein the liquid transport means comprises a liquid transporting strip functioning as the material which, when dry, is substantially opaque but which, when wet, becomes substantially transparent.
13. The assay device of claim 12 above in the liquid transporting strip comprises a porous carrier.
14. The assay device of claim 13 wherein the liquid transporting strip comprises a nitrocellulose strip.

15. The assay device of any one of claims 12 to 14 wherein the coloured portion comprises part of the liquid transporting strip means.
16. The assay device of any one of claims 12 to 14 wherein the coloured portion comprises a sheet applied to the liquid transporting strip means.
17. The assay device of any one of claims 10 to 16 wherein the coloured portion presses against the liquid transporting strip.
18. The assay device of any one of claims 1 to 9 wherein the sample presence signal generation means comprises a mobilisable detectable material localised on or in the liquid transport means, and which, when wetted by the liquid sample, is carried by it along the liquid transport means resulting in a streaked line substantially parallel with the sample flow direction.
19. The assay device of claim 18 wherein the detectable material is a coloured dye.
20. The assay device of any one of claims 1 to 9 wherein the sample presence signal generation means comprises a colour changing material immobilised thereon and which undergoes a change in its visible properties upon wetting.
21. The assay device of claim 20 wherein the colour changing material changes colour in response to wetting by a liquid sample having a specific property to which the colour change material is responsive
22. The assay device of claim 20 or claim 21 wherein the colour changing material is a pH indicator.
23. A method of performing an assay comprising the steps of: contacting an assay device according to any one preceding claim with a liquid sample and, if the sample presence signal is generated, determining whether the test result is positive or negative by reference to the presence or absence of the test signal.